510(k) Summary: FORTIFY™ I Corpectomy Spacers

JUL 3 2012

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
(610) 930-1800
Contact: Sarah Marie Fitzgerald
Project Manager, Regulatory Affairs

Date Prepared: May 31, 2012

Device Name: FORTIFY Integrated Corpectomy Spacers
(FORTIFY™ I and FORTIFY™ I-R)

Classification: Per 21 CFR as follows:
§888.3060 Implant, fixation, spinal intervertebral body fixation orthosis devices
Product Code MQP.
Regulatory Class II, Panel Code 87.

Predicate(s): FORTIFY™ Corpectomy Spacers (K112756)
Ulrich Add^{Plus}™ (K090841)

Purpose:
The purpose of this submission is to request clearance for the FORTIFY Integrated Corpectomy Spacers.

Device Description:
FORTIFY™ and FORTIFY™ Integrated Corpectomy Spacers are vertebral body replacement devices used to provide structural stability in skeletally mature individuals following corpectomy or vertebrectomy. The components include a central core and endplates which are available in a range of sizes and options to accommodate the anatomical needs of a wide variety of patients. The core and endplates can be preoperatively or intraoperatively assembled to best fit individual requirements. Each spacer has an axial hole to allow autogenous bone graft or allograft to be packed inside of the spacer. Protrusions (teeth) on the superior and inferior surfaces grip the endplates of the adjacent vertebrae to resist expulsion. Additional spikes are available on some implants. FORTIFY™ Integrated endplates have an integrated plate to accommodate screws for additional fixation, and are assembled to the core.

FORTIFY™ and FORTIFY™ I Corpectomy Spacers are manufactured from titanium alloy per ASTM F136 and F1295. FORTIFY™-R and FORTIFY™ I-R Corpectomy Spacers are manufactured from radiolucent PEEK OPTIMA LT1, with titanium alloy and tantalum components, per ASTM F2026, F136, F1295, and F560. Screws are manufactured from titanium alloy per ASTM F136 and F1295, with or without hydroxyapatite coating per ASTM F1185.

Indications for Use:
FORTIFY™ Integrated Corpectomy Spacers (FORTIFY™ I and FORTIFY™ I-R) are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). These devices are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacers can be packed with autogenous bone graft or allograft. These spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

Performance Data:
Mechanical testing (static & dynamic compression, static & dynamic torsion, expulsion, and screw pushout) was conducted in accordance with "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s", May 3, 2004 and ASTM F2077 to demonstrate substantial equivalence to the predicate system(s).

Basis of Substantial Equivalence:
FORTIFY™ Integrated Corpectomy Spacers implants are similar to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject spacer to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 3 2012

Globus Medical, Inc.
% Ms. Sarah Marie Fitzgerald
Project Manager, Regulatory Affairs
2560 General Armistead Ave.
Audobon, Pennsylvania 19403

Re: K121107
Trade/Device Name: FORTIFY Integrated Corpectomy Spacers
(FORTIFY I and FORTIFY I-R)
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: June 4, 2012
Received: June 5, 2012

Dear Ms. Fitzgerald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K121107

Device Name: FORTIFY™ Integrated Corpectomy Spacers

Indications:

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Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121107